4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0169]

Draft Guidance for Industry and Review Staff on Pediatric Information Incorporated Into Human Prescription Drug and Biological Products Labeling; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry and review staff entitled "Pediatric Information Incorporated into Human Prescription Drug and Biological Products Labeling." This draft guidance is intended to assist applicants and FDA review staff in making decisions about the placement and content of pediatric information in human prescription drug and biological products labeling in accordance with the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), as well as FDA prescription drug and biological product labeling regulations.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration,

10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002, or the Office of Communication, Outreach, and Development (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Matthew Bacho,

Center for Drug Evaluation and Research,

Food and Drug Administration,

10903 New Hampshire Ave.,

Bldg. 22, rm. 6420,

Silver Spring, MD 20993-0002,

301-796-0067;

or

Stephen Ripley,

Center for Biologics Evaluation and Research (HFM-17),

Food and Drug Administration,

1401 Rockville Pike, suite 200N,

Rockville, MD 20852,

301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry and review staff entitled "Pediatric Information Incorporated into Human Prescription Drug and Biological Products Labeling." In July 2012, FDASIA (Public Law 112-144) reauthorized and made permanent the BPCA and PREA. The goal of both the BPCA and PREA is to provide pediatric information in drug labeling to encourage the appropriate use of drugs in treating pediatric patients.

Data submitted in response to a pediatric Written Request under the BPCA and assessments submitted in response to a PREA study requirement must be described in labeling, whether the findings are positive, negative, or inconclusive (sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(a) and 21 U.S.C. 355(c)) as amended by FDASIA). In addition, when pediatric studies under PREA are fully or partially waived by FDA because there is evidence that a drug would be ineffective or unsafe in a pediatric population or pediatric subpopulation, the safety concern or lack of efficacy must be reflected in the prescription drug labeling (section 505B(a)(4)(D) of the FD&C Act). All useful information on the use of drugs and biological products in the pediatric population should be consistently placed in the proper sections within prescription labeling so that the information is clear and accessible to health care providers.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on incorporating pediatric information into human prescription drug and

biological products labeling. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910-0572.

III. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

IV. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm, or http://www.regulations.gov.

Dated: February 22, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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